DEPARTMENT OF HEALTH & HUMAN SERVICES

94724d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 27, 2004 WL-35-04

Richard A. Ghio, President
Anthony's Fish Grotto Inc.,
d.b.a Ghio Seafood Products
5232 Lovelock Place
San Diego, CA 92110

Dear Mr. Ghio:

During the 12/29-30/03 & 1/02/04 inspection of your manufacturing facility located in San Diego, CA, we observed serious deviations from FDA's Seafood Hazard Analysis and Critical Control Point (HACCP) regulations, 21 Code of Federal Regulations, Part 123 (21 CFR Part 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly several of your fishery products are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However your firm does not have HACCP plans for stuffed salmon, refrigerated, ready to eat seafood salad, smoked albacore tuna spread, and the smoked

salmon spread to control the hazard of pathogen growth and toxin formation.

2. You must have a HACCP plan that, at a minimum, lists the critical control points to comply with 21 CFR 123.6 (a) and (c) (2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for Scombroid (histamine-forming) species of fresh fish does not list the critical control point of product storage for controlling the food safety hazard of histamine formation resulting from time/temperature abuse.

3. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point (CCP) to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plans have inadequate or incomplete critical limits that are not adequate to control the identified food safety hazards as follows:

   a) The critical limit, "[redacted] at the receiving CCP in your firm's HACCP plan for "Fish Fillets, Fresh and Frozen, Scombroid Species" is not adequate to control the hazard of histamine for product that is received from harvest vessels. If vessel operators have implemented HACCP controls, FDA recommends monitoring harvest vessel records in combination with dockside internal temperatures and sensory analysis. Alternatively you can conduct histamine testing combined with dockside internal temperatures and sensory analysis. For recommended primary processor controls, please refer to the guidance in the FDA Fish & Fisheries Products Hazards & Controls Guidance: Third Edition, chapter 7.

   b) Likewise, the critical limit, "[redacted]" at the receiving CCP in your firm's HACCP plan for "Fish Fillets, Fresh and Frozen, Scombroid Species" is not adequate to control the hazard of histamine formation for products received from other processors. FDA recommends records that show that the product was held at or below 40° F throughout transit as an adequate critical limit at receipt. This can be accomplished by monitoring the internal temperature of the product or the ambient temperature in the carrier(s) throughout the transit period. Alternatively, if the product is shipped on ice, FDA recommends that you monitor the adequacy of ice or gel refrigeration at receipt.

   Note that implementation of this critical limit involves proper monitoring of a sufficient number of containers to represent all of the product received and appropriate verification procedure to ensure that this measure is providing adequate control of product temperature.

c) The critical limit, "[redacted] at the brining critical control point in your HACCP plan for "Hot smoked fish" is not adequate to control the hazard of pathogen growth and toxin formation. In a discussion with the investigator, you identified brine to fish ratio as a parameter critical to the process, but this parameter is not listed in the HACCP plan nor is it monitored.

4. You must implement the record keeping system that you listed in your HACCP plans to comply with 21 CFR 123.6(b). However, your firm had no monitoring records for your White (Clam) Chowder HACCP plan at the "Filling and Sealing" CCP for container seal integrity checks.

5. You must take corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). Sections 123.7(b) and (c) require that a corrective action ensures that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation and that the cause of the deviation is corrected. However, your firm did not take a corrective action in the following instances:

   a) Five lots of hot-smoked fishery products between 11/06/03 and 12/19/03 did not meet the [redacted] minimum smoking time [redacted] at the "Smoking-Cooking" CCP.

   b) Based on the processing document entitled, "HACCP-Hot Smoked Fish Test Verification," one lot brined on 01/28/03 did not meet the minimum brine soak time [redacted] according to the "Brining" CCP.

   c) According to your HACCP receiving log, the receiving temperature of fresh tuna exceeded your maximum allowable temperature [redacted] on 11/12/03.

6. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However:

   a) Your firm's HACCP plans for hot-smoked, vacuum packed fish lists a monitoring procedure/frequency at the "Smoking-Cooking" CCP that is not adequate to control the hazard of *Clostridium botulinum* growth and toxin formation. For example, you record time when the smoker alarm indicates that internal temperature has reached [redacted] and then you open the door to the smoker and take the internal temperature of a fish portion with a hand held thermometer. You then shut the door, wait [redacted] and then open the door to check the temperature again. This monitoring method does not insure that the process has met your critical limit [redacted] because it does not show that temperature was maintained throughout the time period. In addition, the heat lost when the smoker door is open increases the chance

of a temperature fluctuation that could cause a critical limit deviation. FDA recommends the use of continuous temperature recording devices that monitor the internal temperatures from the centers of the three thickest portions.

b) Your firm's HACCP plan for clam chowder lists a monitoring procedure at the mixing, blending and cooking critical control point that is not adequate to control the hazard of *Clostridium botulinum* growth and toxin formation. Specifically, your HACCP plan lists a critical limit [redacted] to be monitored by thermometer and clock at the end of the cooking process. At the end of the inspection you submitted adjustments to your HACCP plan that listed: Recording: [redacted] This monitoring method is inadequate to show that temperature was maintained throughout [redacted] There is no margin of safety for heat fluctuation, nor time and temperature recording errors. FDA recommends continuous recording of the soup temperature during the cook process.

c) Your firm is using a monitoring procedure for your seafood cooler at the storage CCP for your histamine forming fish and your clam chowder that is inadequate to control the hazards of pathogen growth, toxin formation, and histamine formation in your various seafood products. Your firm is monitoring temperature of the seafood cooler [redacted] during operation but not monitoring [redacted] each night. FDA reviewed your tests of fillet temperature when the cooler is turned off and the door open. In your test, the core fillet temperature increased [redacted] and the cooler temperature increased [redacted] in the [redacted] period between [redacted] and [redacted] Therefore, if the cooler temperature met your critical limit [redacted] during one of the [redacted] checks, the temperature could subsequently rise [redacted] before the next temperature check, and the fillet temperature would exceed [redacted] In addition, the study was not based on worst case assumptions such as maximum outside temperature, warmest spot in the cooler, thinnest fillets, etc.

d) Your firm's HACCP plans for hot-smoked, vacuum packed fish lists a monitoring procedure/frequency at the "Smoking-Cooking" CCP to that is not adequate to document a continuous cooking temperature. Your current monitoring procedure documents only the starting and stopping times for the cooking step, instead of a continuous record showing that the minimum temperature [redacted] has been maintained for a minimum [redacted] minutes.

7. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor:

a) Safety of water that comes into contact with food or food contact surfaces as evidenced by a lack of backflow protection from piping systems that discharge water. Specifically, hose spigots in the fish market processing area and in the smoking room

lack anti-siphon valves or other backflow prevention devices. Back flow prevention is important in a plant mixing a variety of ready-to-eat products.

b) Condition and cleanliness of food-contact surfaces as evidenced by the observation on 12/29/03 that three employees were observed not washing or sanitizing their hands after a break and prior to returning to processing fresh salmon fillets. Furthermore, on 12/30/03, the investigator observed six employees that also did not wash and sanitize their hands prior to returning to work on fresh salmon fillets.

c) Prevention of cross contamination as evidenced by the accumulation of dried fish residue and grime on the door handle to the fish cooler box.

d) Protection of food contact surfaces from adulteration as evidenced by our finding on 12/29/03 of a high level (350 ppm) of chlorine in the chlorine sanitizing solution that you purportedly use to sanitize food processing utensils and food contact surfaces. Chlorine concentrations for food-contact surfaces above 100-200 ppm should be followed with a rinse.

e) Proper labeling, storage, and use of toxic compounds as evidenced by a pump-style spray bottle containing a 200 ppm chlorine solution was not labeled to identify the contents.

8. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However your firm did not maintain sanitation monitoring records that included safety of water; proper labeling, storage and use of toxic compounds; and control of employee health conditions.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

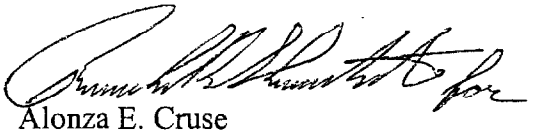
Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as HACCP plans, monitoring forms and recent monitoring data or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

If you have any specific questions regarding this letter, please contact Mr. Robert B. McNab, Compliance Officer at (949) 608-4409. Your written reply should be addressed to:

Pamela B. Schweikert
Director, Compliance Branch
U. S. Food and Drug Administration
19701 Fairchild
Irvine, California 92612-2445

Sincerely,



Alonza E. Cruse
District Director